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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,824	03/23/2005	Alain Rambach	37991-0035	6976

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EXAMINER	
PETERSEN, CLARK D	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,824	RAMBACH ET AL.	
	Examiner	Art Unit	
	Clark D. Petersen	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 and 14-16 are pending in the instant application.

Claims 1-12 and 14-16 were examined on their merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 10, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant (U.S. Patent #5,650,290, issued July 22, 1997). Grant teaches a medium for selection of *E. coli* bacteria. This medium contains Cefsulodin, which is a third generation cephalosporin (see column 5, lines 35-46, for example). This medium also contains the chromogenic substrate 5-bromo-4-chloro-3-indolyl-β-D-glucuronide (see column 6, lines 45-50, for example). This substrate is cleaved by enzymes generated by *E. coli*, and upon cleavage, the substrate releases a visually detectable dye. Therefore the medium selects for bacteria that can both resist Cefsulodin and can generate an enzyme to generate a detectable dye. Additionally, this medium contains at most 1% sodium chloride (see column 7, item 6, lines 47-48, for example) and a concentration of 5-bromo-4-chloro-3-indolyl-β-D-glucuronide ranging in amounts at or greater than .001 g/L. Lastly, Grant teaches that the medium can be a solid form, and

in this form individual colonies can be detected by their color change and counted after inoculation (see column 6, lines 4-26, for example). Therefore the teachings of Grant are deemed to anticipate claims 1, 8, 10, and 14 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant (U.S. Patent #5,650,290) in view of Merlino et al (J Clin Microbiol, 2000). The teachings of Grant are discussed above and applied as before.

Grant does not teach a medium for detecting meticillin-resistant staphylococci. Nor does Grant teach that that the species is specifically *Staphylococcus aureus*.

Merlino et al teach that meticillin-resistant *Staphylococcus aureus* can be detected by plating on the solid medium CHROMagar, which contains a proprietary mix of chromogenic agents that change color when metabolized by *Staphylococcus aureus* (see Introduction, p. 2378, for example). They report that methicillin-resistant bacteria reliably grew on methicillin/oxacillin-doped plates, and that the color change afforded by the CHROMagar medium reliably discerned between *S. aureus* and non-staphylococcal species (see Results, p. 2380, col. 1, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to test *S. aureus* as taught by Merlino et al in a method of detecting antibiotic resistant microorganisms taught by Grant, because Merlino et al teach that antibiotic resistance of *S. aureus* can be detected by plating *S. aureus* on media containing a chromogenic substrate and an antibiotic, and detecting both the growth (indicating antibiotic resistance) and color change (identifying the resistant bacteria as *S. aureus*), and Grant teaches that bacteria can also be detected with a third generation cephalosporin and an appropriate chromogenic substrate. One would be motivated to do so for the expected benefit that one could reliably and specifically detect antibiotic resistant *S. aureus* strains.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Claims 1, 3, 7, 8, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant (U.S. Patent #5,650,290) in view of Rambach (PCT Pub No. WO00/53799, published Sep. 14, 2000). The teachings of Grant are discussed above and applied as before.

Grant does not teach that the chromogenic agent to be used in the meticillin-resistance medium is 5-bromo-4-chloro-3-indoxyl glucoside or 5-bromo-4-chloro-3-indoxyl phosphate, or 5-bromo-4-chloro-3-indoxyl galactoside.

Rambach teaches that each of the above chromogenic dyes can be used to detect growth of *S. aureus*, which generates a different color in the presence of the substrate than other Staphylococcus species in particular, and other bacterial species generally (see column 2, lines 12-17; see column 2 lines 32-39, as examples). Additionally Rambach expressly endorses adding two or all three chromogenic substrates together for optimal detection of *S. aureus* (see lines 32-39, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use chromogenic substrates for detecting *S. aureus* as taught by Rambach in a method of detecting antibiotic resistant microorganisms taught by Grant, because Rambach teaches that *S. aureus* can be specifically identified by growing on the chromogenic substrates identified in his patent publication, and Grant teaches that antibiotic-resistant strains of a particular species of bacteria can be detected by combining chromogenic substrates with a third generation cephalosporin in a growth medium. One would be motivated to do so for the expected benefit that one could not only reliably and specifically detect *S. aureus* strains in particular, but also those that are resistant to third generation cephalosporins, for example.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant in view of Vouillamoz et al ((Antimicrob Agents Chemother, 2001). The teachings of Grant are discussed above and applied as before.

Grant does not expressly teach the detection of microorganisms with a chromogenic medium comprising cefamandole.

Vouillamoz et al teach that one can treat rats infected with experimental endocarditis, which is an infection of *S. aureus* in cardiac tissue, with cefamandole, and that, in fact, it represents a normal course of treatment for endocarditis in humans (see Abstract, p. 1789, for example). They report that this drug alone can be useless against a resistant strain (see Results, text, col. 2, and Fig. 4, p. 1793, as examples).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibiotic cefamandole in a method of determining its inhibition of *S. aureus* growth as taught by Vouillamoz et al in a method of detecting antibiotic resistant microorganisms taught by Grant, because Vouillamoz et al teach that cefamandole is an antibiotic typically used to treat human cases of endocarditis and that *S. aureus* strains exist that are resistant to cefamandole, and Grant teaches that antibiotic-resistant strains of a particular species of bacteria can be detected by combining chromogenic substrates with a third generation cephalosporin in a growth medium. One would be motivated to do so for the expected benefit that one could not only reliably and specifically detect *S. aureus* strains in particular, but also those that are resistant to cefamandole, an antibiotic which is otherwise a normally administered in clinical cases of endocarditis.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Claims 1, 5, 6, 9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant (U.S. Patent #5,650,290) in view of Aritaka et al (Antimicrob Agents Chemother, 2001). The teachings of Grant are discussed above and applied as before.

Grant does not expressly teach the use of cephamycin, oxacephem, a more specific variety of either, or combination with vancomycin, and therefore obviously does not teach specific amounts to include in a selective medium.

Aritaka et al teach that an important feature of *S. aureus*, a dangerous clinical pathogen, is the emergence of antibiotic resistant strains, including the strain Mu3 (see p. 1293, col. 2, for example), which is heterogeneously resistant to vancomycin. They note that a clinically important question is whether to treat vancomycin resistant *S. aureus* infections additionally with a β-lactam antibiotic (see pp. 1293-4, for example). They teach that they can combine vancomycin with third-generation cephalosporins such as cefoxitin and cefmetazole in a medium and test for the growth of antibiotic resistant strains of *S. aureus*, and test whether it is a good combination for fighting clinical infections (see text and Table 1, p. 1293, as examples). They include vancomycin in the medium in amounts ranging from 0 to 8 mg/L and amounts of a second antibiotic in amounts ranging from 0 to 1 mg/L (see p. 1292, col. 2, for example).

They conclude that combination of vancomycin and the cephalosporins actually negated the effect of either, allowing bacteria to grow faster (see Table 1, p. 1293, for example).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various antibiotics such as vancomycin, cefoxitin and cefmetazole in a method of determining their inhibition of *S. aureus* growth as taught by Aritaka et al in a method of detecting antibiotic resistant microorganisms taught by Grant, because Aritaka et al teach that *S. aureus* strains exist that are resistant to various antibiotics, and that it is important to test these strains against other antibiotics and combinations of antibiotics before use in the clinic, and Grant teaches that antibiotic-resistant strains of a particular species of bacteria can be detected by combining chromogenic substrates with a third generation cephalosporin in a growth medium. One would be motivated to do so for the expected benefit that one could not only reliably and specifically detect *S. aureus* strains in particular, but also those that are resistant to third generation cephalosporins and combinations of antibiotics whose efficacy might not be predictable.

Based upon the teachings of the cited references, the level of skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571)272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
7/20/2006

Terry a McKelvey

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